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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/542,449

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James Edward Eyles

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

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01/15/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/542,449	<b>Applicant(s)</b> EYLES ET AL.	
	<b>Examiner</b> Rodney P. Swartz, Ph.D.	<b>Art Unit</b> 1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 6November2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 17-25 and 28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-25,28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 6 November 2008, is acknowledged.

Claim 17 has been amended. Claim 27 has been cancelled. New claim 28 has been added.

2. Claims 17-25 and 28 are pending and under consideration.

### **Rejections Moot**

3. The rejection of claim 27 under 35 U.S.C. 112, second paragraph, is moot in light of the cancellation of the claim.

### **Claim Rejections - 35 USC § 112**

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Newly added claim 28 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Newly added claim 28 lists biodegradable microspheres of an average diameter of from "0.5 to 5 mm". This range is considered new matter because neither the specification nor the claims, at the time of filing, recited a range with this upper size limit.

### Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 17-25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eyles et al (*Vaccine*, 19:4732-4742, 2001) in view of (Zeng et al, *International Journal of Pharmaceutics*, 124:149-164, 1995).

The claims are drawn to a method of producing a protective immune response against a pathogen in a mammal comprising administration to a lung of said mammal a protective amount of biodegradable microspheres of average diameter 0.5—5  $\mu\text{m}$  comprising a nonliving reagent which produces a protective immune response in said mammal.

Eyles et al teach a formulation comprising biodegradable microspheres of 1.5  $\mu\text{m}$  average diameter comprising *Y. pestis* V antigen and intranasal administration of said microsphere composition. (abstract; Methods and Materials, pages 4733-34). However, Eyles et al do not teach administration of said composition to a lung of the mammal.

Zeng et al do teach the advantage of controlled delivery of compositions to the lung of recipients by various biodegradable microspheres, including poly(lactic acid), by aerosolization and inhalation (Abstract; section **3. Biodegradable microspheres**, pages 154-156).

Thus, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to utilize the aerolization/inhalation techniques of Zeng et al in order to increase the efficacy of the composition of Eyles for reaching the lungs of recipients.

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8. Claims 17-19, 22-25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowell et al (*Infection and Immunity*, 64(5):1706-1713, 1996) in view of (Zeng et al, *International Journal of Pharmaceutics*, 124:149-164, 1995).

The claims are drawn to a method of producing a protective immune response against a pathogen in a mammal comprising administration to a lung of said mammal a protective amount of biodegradable microspheres of average diameter 0.5—5  $\mu\text{m}$  comprising a nonliving reagent which produces a protective immune response in said mammal.

Lowell et al teach a formulation comprising proteosomes comprising *Staphylococcus* enterotoxin B toxoid and intranasal administration of said proteosome composition which elicited higher levels of antibody in the lung than the toxoid not in proteosomes. (Abstract; Methods and Materials, pages 1707-1708; section **Enhancement of anti-SEB IgA in bronchial secretions by intranasal immunization with proteosome-SEB toxoid (Fig. 3A)**, page 1709).

However, Lowell et al do not teach administration of said toxoid in biodegradable microspheres to a lung of the mammal.

Zeng et al do teach the advantage of controlled delivery of compositions to the lung of recipients by various biodegradable microspheres, including poly(lactic acid), by aerosolization and inhalation (Abstract; section **3. Biodegradable microspheres**, pages 154-156).

Thus, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to utilize the aerolization/inhalation techniques of Zeng et al in order to increase the efficacy of the composition of Lowell for reaching the lungs of recipients.

### Conclusion

9. No claims are allowed.

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10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

January 15, 2009